

## **510 (K) SUMMARY**

This summary of 510(K) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21CFR 807.92.

1. **Submitter's Identification:**

Zibo Intco Medical Products, Co. Ltd.  
No. 18, Qingtian Road.  
Qilu Chemical Industry Park  
Zibo, Shandong Province  
China

Date summary prepared: March 23, 2014

2. **Name of the Device:**

Zibo Intco Medical Products, Co. Ltd.  
Powder-free Vinyl Patient Examination Gloves. Yellow Color

3. **Common name/classification name of the Device:**

Powder-Free Vinyl Patient Examination Gloves, Yellow Color

4. **Contact Person:**

Jennifer Guo, Tel: 909-548-4828

5. **Predicate Device Information:**

Shijiazhuang Hongxiang Plastic Products Ltd.  
Synthetic Vinyl Patient Examination Gloves – Powder Free (K992821)

6. **Device Description:**

Classified by FDA's General and Plastic Surgery Device panel as Class I, 21 CFR 880.6250, Powder-Free Vinyl Patient Examination Glove, 80LYZ, and meets all requirement of ASTM Standard D5250-06.

7. **Intended Use:**

A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or finger to prevent contamination between patient and examiner.

8. **Comparison to Predicate Devices:**

Zibo Intco Medical Products, Co. Ltd. Powder-free Vinyl Patient Examination Gloves, Yellow Color are substantially equivalent in safety and effectiveness to the Shijiazhuang Hongxiang Plastic Products Co., Ltd. (K992821) and Shanghai Jiawang Industrial Co., Ltd. (K031854)

9. **Discussion of Non-Clinical tests performed for Determination of Substantial Equivalence are as follows:**

The standards used for Zibo Intco Medical Products, Co. Ltd. glove production are based on ASTM-D-5250-06. All testing meets requirements for Physical and Dimensions Testing conducted on gloves, Inspection Level S-2, AQL 2.5.

The FDA 1000 ml. Water Fill Test was also conducted with samplings of AQL 2.5, Inspection Level I, meeting these requirements. Primary Skin irritation and Skin Sensitization (allergic contact dermatitis) testing was conducted with results showing no primary skin irritant or sensitization reactions.

There are no special labeling claims and we do not claim our gloves as hypoallergenic is conducted to insure that our gloves meet our "powder-free" claims (contain no more than 2 mg powder per glove).

10. **Discussion of Clinical Tests Performed:**

Not Applicable – There is no hypoallergenic claim.

11. **Conclusions:**

Zibo Intco Medical Products, Co. Ltd. Powder-free Vinyl Patient Examination Gloves, Yellow Color conform fully to ASTM-D-5250-06 standard as well as applicable 21 CFR references, and, meets pinhole FDA requirements, biocompatibility requirements and labeling claims as shown by data in Section 7. There are no safety/efficacy issues or new claims from the "substantial equivalence" products cited.

**Table 7-2. Side-by-Side Comparison of Intended Use, Design, Material, Physical, Biocompatibility, and Performance Testing**

	<b>Proposed Device</b>	<b>Predicate Device (K992821)</b>
<b>Description</b>	Zibo Intco Medical Products, Co. Ltd Powder-Free Vinyl Patient Examination Gloves, Yellow Color	Shijiazhuang Hongxiang Powder-free Vinyl Patient Examination Gloves
<b>Product Code</b>	LYZ	LYZ
<b>Indications for Use</b>	A disposable device intended for medical purposes that is worn upon the examiner's hands or fingers to prevent contamination between patient and examiner.	Substantially equivalent
<b>Type of Use</b>	Over-The-Counter Use	Substantially equivalent
<b>Labeling: Instruction for use</b>	A garment covering the hand and wrist area. Clovers have separate openings for each finger and the thumb.	Substantially equivalent
<b>Labeling: Labels on the carton</b>	Labels include: Product name; color; "single use Only" size, piece count, lot number, distributor name, and manufacturer address.	Substantially equivalent
<b>Device Materials</b>	Poly Vinyl Chloride Polyurethane Diisononyl Phthalate (DINP)	Substantially equivalent
<b>Before Aging: Tensile, Strength(Mpa) and Ultimate Elongations</b>	Average Tensile Strength (Mpa): 19.2 Average Ultimate Elongations: 501%	Substantially equivalent
<b>After Aging: Tensile Strength(Mpa) and Ultimate Elongations</b>	Average Tensile Strength (Mpa): 16.8 Average Ultimate Elongations: 472%	Substantially equivalent
<b>Overall Length on Medium Size</b>	Average over 249mm	Substantially equivalent
<b>Width of Palm on Medium Size</b>	Average 95mm	Substantially equivalent
<b>Palm Thickness</b>	Average 0.085 mm	Substantially equivalent
<b>Figure Thickness</b>	Average 0.088 mm	Substantially equivalent

Residual Powder	According to ASTM D6124-06 Standard Test Method for Residual Powder on Medical gloves for the determination of residual powder content. Testing result indicates the weight of all types of residual or powder on finished powder-free gloves as < 2 mg per glove and there is no defect glove found according to ASTM D6124-06.	Substantially equivalent
Pinhole Results	According to ASTM D5151-06, Testing result indicates pinhole were found less than two pieces gloves out of 125 pieces gloves. AQL 2.5 is met.	Substantially equivalent
Biocompatibility Result: Primary Skin Irritation	Not an irritant	Substantially equivalent
Dermal Sensitization	Not a sensitizer	Substantially equivalent
Summary of comparison	Zibo Intco Medical Products, Co. Ltd Powder-Free Vinyl Patient Examination Gloves, Yellow Color (subject device) and Shijiazhuang Hongxiang Powder-free Vinyl Patient Examination Gloves (predicate device) are substantially equivalent in all technological characteristics, including tensile strength, ultimate elongations size, thickness, residual powder and pinhole.	



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

May 1, 2014

Zibo Intco Medical Products Company, Limited  
C/O Frank Liu  
Basic Medical Industries, INC  
12390 East End Avenue  
Chino, California 91710

Re: K132637

Trade/Device Name: Powder – free Vinyl Patient Examination Gloves, Yellow Color  
Regulation Number: 21 CFR 880.6250  
Regulation Name: Patient Examination Gloves  
Regulatory Class: I  
Product Code: LYZ  
Dated: March 24, 2014  
Received: March 27, 2014

Dear Mr. Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

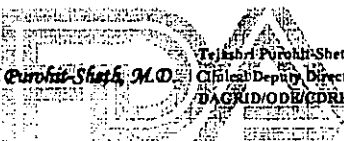
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Tejaswri Purohit-Sheth, M.D.  
Clinical Deputy Director  
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.  
Acting Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and  
Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement on last page.

510(k) Number (if known)  
K132637

Device Name  
Powder-free Vinyl Patient Examination Gloves, Yellow Color

Indications for Use (Describe)

A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or fingers to prevent contamination between patient and examiner.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Elizabeth F. Claverie -S  
2014.04.30 15:39:09-04'00'